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1516	Attorneys for Plaintiff				
17 18	UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA				
19 20 21 22 23 24 25 26 27	ASHLEY CARROLL, individually and on behalf of all others similarly situated, Plaintiff, v. MYRIAD GENETICS, INC., Defendant.	Case No. 4:22-cv-00739-YGR SECOND AMENDED CLASS ACTION COMPLAINT JURY TRIAL DEMANDED			
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SECOND AMENDED CLASS ACTION COMPLAINT CASE No. 4:22-cv-00739-YGR

Plaintiff Ashley Carroll ("Plaintiff") brings this action on behalf of herself and all others similarly situated against Defendant Myriad Genetics Inc. ("Defendant" or "Myriad"). Plaintiff makes the following allegations pursuant to the investigation of her counsel and based upon information and belief, except as to the allegations specifically pertaining to herself, which are based upon personal knowledge.

NATURE OF THE ACTION

- 1. This is a putative class action lawsuit on behalf of purchasers of Myriad's Prequel Prenatal Screen ("Prequel" or the "Tests"). Defendant markets and sells the Tests as genetic, prenatal screening tests for pregnant women that screen for various chromosomal and genetic conditions affecting a baby's health. Defendant markets these tests as accurate. Although NIPT testing is generally effective at screening for Down syndrome, NIPT tests return false positive test results for some rare genetic conditions 85 percent of the time or more—sometimes up to 98 percent. Thus, the Tests are worth far less than their market price.
- 2. Prenatal testing in recent years has moved towards non-invasive methods to determine the fetal risk for genetic disorders, including Non-Invasive Prenatal Testing ("NIPT").²
- 3. NIPT analyzes DNA fragments from the blood of a pregnant women to estimate the risk that the fetus will be born with certain genetic abnormalities, including chromosomal disorders like Down Syndrome and Trisomy 18, or other, more rare disorders, like Patau syndrome (Trisomy 13), Prader-Willi, and Angelman syndrome.
- 4. NIPT is incredibly popular. However, many of these tests are often unreliable, giving pregnant women false positive results for genetic conditions that their fetuses do not have.
- 5. In fact, a recent *New York Times* investigation found that for every 15 times an NIPT screening correctly identifies a fetal disorder, the screening is wrong 85 times, meaning

¹ https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html

² https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6545823/

that 85 percent of all positive results are false positives.³ These problems extend to Defendant's Test, the Prequel, and encompass a number of conditions that Prequel tests for, such as Trisomy 13, microdeletions, DiGeorge syndrome, and monosomy X.

- 6. Despite this unreliable testing, Defendant falsely advertises their findings as reliable, accurate, offering peace of mind for consumers regarding the viability of their pregnancies, and that consumers should have "total confidence" in the results. Defendant also fails to disclose the false positive rates and distinct unreliability of the Prequel. These unreliable test results—such as false positives—can lead to devastating personal consequences and painful decisions that are premised upon this wrong information.
- 7. Plaintiff and Class Members purchased the Tests designed, marketed, manufactured, distributed, and sold by Defendant as reliable. Plaintiff and Class Members would not have purchased Defendant's Tests—or, at minimum, would have paid significantly less for the Tests—had they known the Tests were unreliable. Plaintiff and Class Members thus suffered monetary damages as a result of Defendant's deceptive and false representations.

PARTIES

8. Plaintiff Ashley Carroll is a resident of Menlo Park, California and has an intent to remain there, and is therefore a domiciliary of California. In or about June 2021, Plaintiff visited her doctor's office in California, where she received a brochure about Defendant's Myriad Prequel Test. *See* ECF No. 30 (Defendant's brochure). The brochure made representations regarding the Prequel generally, including that Prequel by default tests for Down syndrome (Trisomy 21), Edwards Syndrome (Trisomy 18), and Patau Syndrome (Trisomy 13). The brochure also represented that the Prequel Test is "more accurate than maternal serum screening" and will "reduc[e] the chances you'll need an unnecessary invasive follow-up test." Plaintiff also reviewed Defendant's website, which made additional representations about the Prequel, including that Prequel "has the lowest test failure rate in the industry, which translates to a lower chance of

³ https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html

needing a repeat test or an unnecessary invasive diagnostic procedure," and that she should have "total confidence in every result." As described throughout this Complaint, these representations did not distinguish between the various conditions Prequel tested for. Based on these representations and warranties, Plaintiff understood and Defendant represented that the Prequel was a reliable test for each and every one of the conditions it tested for.

- 9. After reviewing Defendant's brochure and website, Plaintiff purchased Defendant's Prequel with AMPLIFY technology (as described below) in California based on Defendant's representations that the Test was reliable, as described above and throughout this Complaint. Plaintiff purchased the default option for the Prequel—which tested for Trisomy 13, Trisomy 18, and Trisomy 21—as well the sex chromosome testing add-on. Plaintiff paid \$295 out of pocket for the Prequel. Plaintiff relied on Defendant's representations and warranties in deciding to purchase the Prequel, including those representations described above and throughout this Complaint. Accordingly, Defendant's representations and warranties were part of the basis of the bargain, in that she would not have purchased the Prequel on the same terms, or at least would have paid significantly less for the Prequel, had she known the Test's representations about reliability, accuracy, and trustworthiness were not true as to Trisomy 13.
- 10. Defendant Myriad Genetics, Inc. is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business in Salt Lake City, Utah. Myriad is a molecular diagnostic company specializing in genetic tests that determine the risk of developing disease, assess the risk of disease progression, and guide treatment decisions.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction pursuant to 28 U.S.C § 1332(d)(2)(a) because this case is a class action where the aggregate claims of all members of the proposed class are in excess of \$5,000,000.00, exclusive of interest and costs, there are over 100 members of the putative class, and Plaintiff, as well as most members of the proposed class, are citizens of states different from Defendant.

- 12. This Court has personal jurisdiction over Defendant because it conducts substantial business within California, such that Defendant has significant, continuous, and pervasive contacts within the State of California and because a substantial portion of the events that gave rise to this cause of action occurred here.
- 13. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) because Defendant transacts significant business within this District and because Plaintiff purchased and used the Prequel Test in this District.

FACTUAL ALLEGATIONS

- I. Defendant Represents Prequel Is Reliable To Test For Various Genetic Conditions, Such As Trisomy 13 And Microdeletions
- 14. Prenatal testing is used to assess a pregnant patient's risk of carrying a child with chromosomal disorders that can affect the baby's health. When tests provide accurate information, prenatal genetic testing provides valuable information to pregnant patients about the health of their unborn child. The genetic conditions these tests are directed towards can make a pregnancy non-viable or have serious impacts on the health of a surviving newborn, such as structural anomalies, intellectual disabilities, and a shortened lifespan."⁴
- 15. The discovery of fetal DNA in maternal blood has led to changes in prenatal screening. Following this discovery, many companies began working on blood tests, otherwise known as NIPT, aimed at detecting chromosomal abnormalities without the invasive and risky nature of amniocentesis and chorionic villus sampling ("CVS").⁵
- 16. Although historically only offered to patients considered to be high risk because of their age or personal or family history, prenatal screening has expanded significantly in the last decade. NIPT was developed and grew until the ACOG changed its guidance in 2020 to recommend that all pregnant patients "be offered both screening and diagnostic testing options."

⁴ https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html

⁵ https://blog.seracare.com/ngs/evolution-of-non-invasive-prenatal-testing-nipt-testing

⁶ https://www.acog.org/womens-health/infographics/cell-free-dna-prenatal-screening-test_

The ACOG's guidance is that "[t]esting for chromosomal abnormalities should be an informed patient choice based on provision of adequate and accurate information, and the patient's clinical context, accessible health care resources, values, interests, and goals."

- 17. The market for prenatal testing was recently estimated to range from \$600 million and is growing rapidly, with the number of women taking these tests expected to double by 2025.8
- 18. Seeking to capitalize on this expanding market, Myriad first offered its Prequel Prenatal Screen NIPT as a noninvasive blood screen for pregnant women to find out if their babies have an increased risk for chromosomal conditions like Patau syndrome (Trisomy 13), Down syndrome (Trisomy 21) and Edwards syndrome (Trisomy 18). A pregnant patient whose child has one of these conditions faces serious questions about risks in continuing the pregnancy, the viability of the pregnancy, and the prognosis and quality of life for any surviving newborn.
- 19. By default, the Prequel tests for Trisomy 13, Trisomy 18, and Trisomy 21. Since 2019, when Myriad expanded its Prequel testing, women could also choose to test for additional conditions—*e.g.*, microdeletions—and/or the sex of their child.

⁷ *Id*.

⁸ https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html

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Screening options

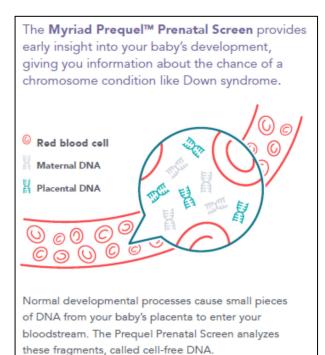
Included with every screen: Trisomy 21 (Down syndrome), Trisomy 18 (Edwards syndrome), Trisomy 13 (Patau syndrome)

Optional panels:

- Sex Chromosome Analysis (SCA): Genetic sex prediction (includes twin pregnancies), Monosomy X (Turner syndrome), Klinefelter syndrome (XXY), Trisomy X (XXX), XYY syndrome
- Microdeletions: 22q11 deletion (DiGeorge syndrome), 1p36 deletion syndrome, 15q11 deletions (Angelman or Prader-Willi syndrome), 4p deletion (Wolf-Hirschhorn syndrome), 5p deletion (Cri-du-Chat syndrome)
- Expanded Aneuploidy Analysis (EAA): Includes analysis of all chromosomes, placental insufficiency (e.g. growth restriction, stillbirth), uniparental Disomy Syndromes (e.g. Prader-Willi), Fetal Syndromes (e.g. Trisomy 8, Trisomy 22)

View full list

- 20. Defendant's brochure and website make uniform representations as to the Prequel generally, other than describing what each condition is. That is, regardless of whether a woman chooses the default Prequel panel or adds on testing for microdeletions, she will see the exact same representations of reliability, and these representations do not distinguish between a test for Down syndrome, a test for Patau syndrome, or a test for microdeletions.
- 21. In its brochure, Myriad represents that the Prequel Test provides "[e]arly insight into your baby's development," that Prequel can allow women to "find out if your baby has an increased risk for a chromosome condition," and gives women "information about the chance of a chromosome condition."





22. The brochure also represents that the Prequel "reduces the need for unnecessary invasive diagnostic tests" because NIPT tests like the Prequel "ha[ve] been shown to be more accurate that maternal serum screening."

Screening reduces the need for unnecessary invasive diagnostic tests

Noninvasive prenatal screening using cell-free DNA has been shown to be more accurate than maternal serum screening, reducing the chances you'll need an unnecessary invasive follow-up test like chorionic villus sampling (CVS) or amniocentesis.

Our results are personalized based on your age and how far along you are in your pregnancy, so you have the clearest picture of your risk, which can help you decide if you'd like to pursue additional testing.

23. The brochure further claims that Prequel "look[s] for the most serious chromosome conditions"—Trisomy 13, Trisomy 18, and Trisomy 21—as well as having the ability to "assess if your baby is missing a tiny piece of a chromosome (called a 'microdeletion'), which can lead to birth defects and intellectual disabilities."

We look for the most serious chromosome conditions

Some babies are born with a different number of chromosomes

Most babies have 46 chromosomes, 23 from each parent. Occasionally, a baby will have an extra chromosome. This is called a trisomy. Babies born with trisomies can have serious health issues, including birth defects, intellectual disabilities and shortened lifespans.

The Prequel Prenatal Screen looks for the three most common trisomies:

- Down syndrome Trisomy 21
- Edwards syndrome Trisomy 18
- Patau syndrome Trisomy 13

Your healthcare provider can help you decide whether you may want to screen for additional conditions

The Prequel Prenatal Screen can also assess if your baby has the correct number of sex chromosomes, which can impact health issues like fertility. Additionally, the screen can assess if your baby is missing a tiny piece of a chromosome (called a "microdeletion"), which can lead to birth defects and intellectual disabilities.

24. The brochure also advertises Prequel as capable of providing patients with peace of mind regarding the viability of their pregnancies by posting customer testimonials praising the Test:



Taking the Prequel Prenatal Screen has helped me sleep better because getting answers — one way or the other — is a huge relief. I truly believe this type of noninvasive, personalized science is the bright future of medicine.

- LACEY O. & SEJIN H.

- 25. Defendant makes similar representations on its website regarding the Prequel generally. For instance, the website represents that a woman can "find out if [her] baby has an increased risk for conditions like Down, Edwards, or Patau Syndromes," can "learn about [her] baby's chance of having a chromosome abnormality leading to a condition like Down syndrome," and that Prequel "can determine the chance that your baby has a chromosome abnormality associated with a certain genetic condition."
- 26. Defendant also represents on its website that Prequel "has the lowest test failure rate in the industry, which translates to a lower chance of needing a repeat test or an unnecessary invasive diagnostic procedure."

Prequel® Prenatal Screen with AMPLIFY™ technology provides results to >99.9% of patients

The Preguel Prenatal Screen has the lowest test failure rate in the industry, which translates to a lower chance of needing a repeat test or an unnecessary invasive diagnostic procedure. We use advanced science and technology that works for pregnant women of all ages, including those with twin and IVF pregnancies.

27. Further, Defendant previously represented on its website (at the time Plaintiff purchased her Test) that women should have "total confidence in every result."

TOTAL CONFIDENCE IN EVERY RESULT

The Prequel Prenatal Screen has the lowest test failure rate in the industry, which translates to a lower chance of needing a repeat test or an unnecessary invasive diagnostic procedure. We use advanced science and technology that works for pregnant women of all ages, including those with twin and IVF pregnancies.

28. As Defendant has tweaked its Test, it has continued to make representations regarding Prequel's reliability. In 2020, Myriad launched its propriety "AMPLIFY" technology, which Myriad claimed further increased the performance and reliability of its Prequel test, thereby reducing the rate of false positive and false negative results.

⁹ This language was taken down following the investigation by *The New York Times*. https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html ("Myriad Genetics advertised 'total confidence in every result' on its prenatal testing website but said nothing about how often false positives can occur. After The Times inquired about these tests, Myriad took down that language.").

29. Nicole Lambert, president of Myriad International, Oncology and Women's Health, claimed:

Prequel already provided *highly accurate* results and this proprietary technology further increases the sensitivity of our test ... With AMPLIFY, Prequel maintains its industry-leading low rate of failed samples—delivering results to 99.9 percent of patients. The important clinical benefits are that each woman who receives the test can expect *highly accurate* NIPS results, regardless of body mass index (BMI), race, or ethnicity."¹⁰

- 30. Again, Defendant makes these representations of reliability and trustworthiness throughout its marketing and advertising campaign. Defendant's brochure, which is distributed to potential purchasers of the Tests, makes the same representations regardless of whether the consumer purchases only the default testing option (Trisomy 13, 18, and 21), or purchases addons like microdeletion testing.
- 31. Thus, as to each condition that Prequel can test for, Defendant represents that Prequel can reliably and accurately test for that condition, such as Trisomy 13, 18, and 21, and microdeletions. And Defendant represents to consumers that they should trust the results they receive for their Test. These representations are uniform and do not differ or distinguish between testing for each condition.
 - 32. Tests like Prequel are costly, with an average out-of-pocket cost of \$279.11

II. Prequel Is Unreliable To Test For A Variety Of Genetic Conditions, Including Trisomy 13 And Microdeletions

- 33. Since the launch of Prequel, Defendant has consistently advertised the Tests as reliable, "highly accurate," and trustworthy. Unfortunately for pregnant women, the Tests are alarmingly inaccurate.
- 34. A recent investigation by *The New York Times* found that despite the NIPT tests—including Prequel—being advertised as "reliable," "highly accurate," and offering "total

¹⁰ https://investor.myriad.com/news-releases/news-release-details/myriad-launches-proprietary-amplifytm-technology-further (emphasis added).

http://www.motherofmicrobes.com/the-nipt-test-costs-less-than-you-think-but-beware-of-insurance-surprises/

confidence" and "peace of mind" for patients, the tests are inaccurate more than 85 percent of the time.

- 35. Specifically, NIPT tests like Prequel cannot reliably discover microdeletions like the ones Defendant claims Prequel can correctly detect. Microdeletions can have a wide range of symptoms, including intellectual disability, a shortened life span, and a high infant mortality rate.
- 36. Beyond microdeletions, *The New York Times* investigation noted that research suggests that NIPT testing for Patau Syndrome (Trisomy 13) and Turner Syndrome (monosomy X) is also unreliable because such testing often results in false positives for these conditions.¹²
- 37. For instance, for Trisomy 13, scientists have warned that "the ability of NIPT to correctly predict a positive result for ... [T]risomy 13 is less than 60%." Another study published in 2015 took the average of three studies and found that the false positive rate for Trisomy 13 is 55.6%, 4 essentially a coin-flip. And an article found that the false positive rate for NIPT testing for Trisomy 13 is approximately 79%. 15
- 38. Further, a study from 2014 found that NIPT screening for Trisomy 13 does more harm than good when offered to a general average-risk pregnant population (as Defendant does) because of the low predictive value associated with the test, the extremely low prevalence of the disease, and the fact that NIPT screening for Trisomy 13 is not associated with a reduction in invasive procedures.¹⁶

¹² See https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html ("The screenings for Patau syndrome (which often appears on lab reports as 'trisomy 13') and Turner syndrome ('monosomy X') also generate a large percentage of incorrect positives, while the screenings for Down syndrome ('trisomy 21') and Edwards syndrome ('trisomy 18') work well, according to experts.").

 ¹³ Jia-Chi Wang, et. al., Discordant Noninvasive Prenatal Testing And Cytogenetic Results: A Study Of 109 Consecutive Cases, 17 GENETICS IN MEDICINE 234, 236 (2015).
 ¹⁴ Id

¹⁵ https://qz.com/646436/prenatal-testing-is-about-to-make-being-pregnant-a-lot-more-stressful/.

¹⁶ Verweij EJ, de Boer MA, Oepkes D., *Non-Invasive Prenatal Testing For Trisomy 13: More Harm Than Good?*, 44 ULTRASOUND IN OBSTETRICS & GYNECOLOGY 112 (2014), https://obgyn.onlinelibrary.wiley.com/doi/epdf/10.1002/uog.13388.

- 39. The market for NIPT is not heavily regulated. "There are few restrictions on what test makers can offer. The FDA often requires evaluations of how frequently other consequential medical tests are right and whether shortfalls are clearly explained to patients and doctors. But the FDA does not regulate this type of test." ¹⁷
- 40. As a result, consumers are easily confused by the marketing of companies like Myriad. According to the *Times*, a former director of the FDA office that oversees many medical tests "reviewed marketing materials from three testing companies and described them as 'problematic'" and "misleading." As the official put it, "These numbers are meaningless." 18
- 41. In addition, in early 2022, a report by the Hastings Center "analyze[d] all available English-language consumer-directed NIPT brochures," and concluded that the communications "substantiate concerns about bias and inaccuracy in the promotion of these screening tests."
- 42. The Hastings Report "raise[d] concerns about the commercial marketing of NIPT, noting that a company's interest in promoting its tests could influence the messages it conveys to consumers," specifically by making the marketing materials "incomplete, unsubstantiated, inaccurate, misleading, or emotive," which compromises "the consumer's ability to make informed choices."
- 43. The Hastings Report went on to state that "[t]he potential for bias in industry-developed information about NIPT, in addition to the lack of regulatory oversight for this type of product, raises questions about clinical communication and appropriate adoption." The Hastings Report also reiterated some of the concerns from the article in *The New York Times*, noting "[p]oor-quality information poses the potential for harm from increased shock, distress,

¹⁷ https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html ¹⁸ *Id.*

¹⁹ Kelly Holloway, et al., *The Market in Noninvasive Prenatal Tests and the Message to Consumers: Exploring Responsibility*, 52 HASTINGS CENTER REPORT 1, 3 (2022), https://s3.documentcloud.org/documents/21411047/simms-ev-feb-9.pdf ("Hastings Report").

²⁰ *Id*. at 1.

²¹ *Id.* at 2.

and confusion upon receipt of a high-chance result and may even lead to termination of an unaffected fetus if the possibility of a false-positive result is not clearly communicated."²²

- 44. Recognizing these concerns, in April 2022, the FDA issued a safety communication about NIPT tests, warning that "Genetic Non-Invasive Prenatal Screening Tests May Have False Results." The statement, directed to "patients and health care providers," emphasizes that "[w]hile health care providers widely use NIPS tests, none have yet been authorized, cleared, or approved by the FDA" and "[t]he accuracy and performance of NIPS tests have not been evaluated by the FDA and these tests can give false results.
- 45. The FDA safety communication noted that the FDA is aware of reports that "pregnant people have ended pregnancies based only on the results of NIPS tests," and stated that "[g]iven the increased use of these tests and concerns raised in recent media reports, the FDA is providing this information to educate patients and health care providers and to help reduce the inappropriate use of NIPS tests."²⁴ It stated that patients and health care providers alike "should be aware of the risks and limitations of using these screening tests," and made specific recommendations for patients and for health care providers to become better informed.
- 46. Finally, the FDA safety communication noted "the risks related to the use of genetic prenatal screening and the potential harm if NIPS test results are not used and interpreted appropriately" and "encourages test developers to provide accurate, clear, and complete information about the performance of their tests, how they should be used, and what the results may or may not mean."
- 47. Myriad's aforementioned representations support the concerns about the marketing of NIPT tests. Not only does Myriad represent that Prequel can reliably test for

²² *Id.* at 3.

²³ https://www.fda.gov/medical-devices/safety-communications/genetic-non-invasive-prenatal-screening-tests-may-have-false-results-fda-safety-communication.

²⁴ *Id*.

²⁵ *Id*.

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various genetic conditions and that women should have "total confidence" in these results, Myriad fails to disclose that NIPT testing such as Prequel is unreliable to test for a number of genetic conditions, such but not limited to Trisomy 13, microdeletions, DiGeorge syndrome, and monosomy X. Myriad does not disclose the high rate of false positives for these tests and does not disclose the low predictive value of testing for these conditions.

- 48. Moreover, Myriad does not meaningfully explain (or explain at all) that "it is crucial that providers and consumers understand that NIPT ... cannot be used as a replacement for invasive prenatal diagnosis."²⁶ Indeed, Myriad says the opposite, representing that consumers should have "total confidence" in results and that Prequel reduces the need for further invasive testing.
- 49. As a result of these false positive screenings, women are forced to undergo the very invasive testing that Defendant claims its Tests help women avoid, including amniocentesis and CVS. During an amniocentesis, a needle is used to remove amniotic fluid from the uterus for testing. Similarly, during a CVS procedure, a catheter or needle is used to biopsy placental cells that are derived from the same fertilized egg as the fetus. Both procedures include an increased risk of miscarriage.²⁷
- Many women also have abortions after obtaining positive results from NIPT 50. screens, even though those results may very well be inaccurate. For example, a 2014 study found that six percent of patients who screened positive obtained an abortion without getting another test to confirm the result.²⁸

²⁶ Jia-Chi Wang, et. al., Discordant noninvasive prenatal testing and cytogenetic results: a study of 109 consecutive cases, 17 GENETICS IN MEDICINE 234, 236 (2015).

²⁷ https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html

²⁸ https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html

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- 51. Moreover, one United Kingdom study in 2017, found that 63% of U.K. women with high-risk NIPT results go to terminate their pregnancies.²⁹
- 52. In addition to the anguish for the potentially compromised health of their child, parents with positive test results also must contend with the prospect of expensive and stressful doctor's appointments with high-risk pregnancy specialists, often incurring increased costs for these extra visits and increased testing.³⁰
- False negatives also have ramifications. For instance, a 2000 study analyzed the 53. impact of receiving a false negative test result based on a systematic review of literature.³¹ The study found that false negatives can lead to "lower parental acceptance of the affected child and with blaming others for this outcome," as well as the delayed detection of underlying conditions. Further, false negatives can "reduce public confidence in screening."
- 54. Consumers are therefore paying hundreds of dollars for testing that is highly inaccurate and untrustworthy.

Defendant's Misrepresentations And Omissions Are Actionable III.

Plaintiff and Class Members were injured because they paid a premium for the 55. Tests or otherwise paid more for the Tests based on Defendant's misrepresentations that the Tests were reliable and Defendant's failure to disclose that the Tests were largely unreliable and inaccurate to test for a number of conditions, such as Trisomy 13 and microdeletions.

²⁹ M. Hill et al., "Has Noninvasive Prenatal Testing Impacted Termination of Pregnancy and Live Birth Rates of Infants with Down Syndrome?," *Prenatal Diagnosis* 37, no. 13 (2017): 1281-90.

³⁰ https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html ("Patients who receive a positive result are supposed to pursue follow-up testing, which often requires a drawing of amniotic fluid or a sample of placental tissue. Those tests can cost thousands of dollars, come with a small risk of miscarriage and can't be performed until later in pregnancy in some states, past the point where abortions are legal.").

³¹ Mark P. Petticrew et al., False-Negative Results in Screening Programmes: Systematic Review of Impact and Implications, 4 HEALTH TECH. ASSESSMENT 1 (2000), https://pubmed.ncbi.nlm.nih.gov/10859208/

- 56. Trusting Defendant's representations, Plaintiff and Class Members bargained for Tests that would provide them with accurate results and were deprived of the basis of their bargain when Defendant sold them a highly inaccurate test.
- 57. No reasonable consumer would expect that a Test marketed as "highly accurate" and trustworthy would be alarmingly inaccurate.
- 58. Plaintiff satisfies the requirements of Rule 9(b) by alleging the following facts with particularity:
- WHO: Defendant made material misrepresentations and/or omission of fact about the Tests through their brochure and website that the Tests were reliable and trustworthy. Defendant made these representations as to the Prequel generally and each condition it tests for, and did not distinguish between the reliably of the tests for certain conditions as opposed to others (*e.g.*, Down syndrome vs. Trisomy 13 and microdeletions).
- WHAT: Defendant's conduct here was, and continues to be, fraudulent because it misrepresents that the Tests are reliable to test for a variety of genetic conditions like Trisomy 13 and microdeletions, and omits that the Tests are unreliable to test for these conditions. Thus, Defendant's conduct deceived Plaintiff and Class Members into believing that the Tests were reliable. Defendant knew or should have known that this information is material to reasonable consumers, including Plaintiff, in making their purchasing decisions, yet they continued to pervasively market the Tests in this manner.
- WHEN: Defendant made material misrepresentations and/or omissions prior to and at the time Plaintiff and Class Members purchased the Tests, despite the fact that Defendant knew or should have known that the testing was highly inaccurate.

 HOW: Defendant made material misrepresentations and/or failed to disclose material
- HOW: Defendant made material misrepresentations and/or failed to disclose material facts regarding the inaccuracy of the Tests.
- WHY: Defendant made the material misrepresentations and/or omissions detailed herein for the express purpose of inducing Plaintiff, Class Members, and all reasonable consumers to purchase and/or pay for the Tests, the effect of which was that Defendant profited by selling the Tests to thousands of consumers.
- **INJURY:** Plaintiff and Class Members, paid a premium, or otherwise paid more for the Tests when they otherwise would not have absent Defendant's misrepresentations and/or omissions.
- 59. It does not matter whether or not Plaintiff and Class Members received a false negative or a false positive result. Plaintiff and the Class's injury is economic: they were charged more than they should have been for a Test that was unreliable but which Defendant represented was reliable, and Plaintiff and the Class would not have purchased the Test or would

have paid significantly had they known the Test was inaccurate and unreliable to test for certain conditions like Trisomy 13. In other words, Plaintiff and Class Members were injured at the time of purchase, not the time they received their results, because an unreliable test like the Prequel Test was worth less to Plaintiff and Class Members than a reliable one.

60. As a result of Defendant's misrepresentations and omissions, Plaintiff brings this action on behalf of herself and the Class for equitable relief and to recover damages and restitution for: (i) breach of express warranty; (ii) breach of implied warranty; (iii) unjust enrichment; (iv) fraud; (v) fraudulent omission; (vi) violation of California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200, et seq.; (vii) violation of California's False Advertising Law ("FAL"), Cal. Bus & Prof Code §§ 17500, et seq.; and (viii) violation of California's Consumers Legal Remedies Act ("CLRA"), Civil Code §§ 1750, et. seq.

CLASS ALLEGATIONS

- 61. Plaintiff seeks to represent a class defined as all persons in the United States who purchased a Prequel test (the "Nationwide Class").
- 62. Plaintiff also seeks to represent a class defined as all persons who reside in the state of California who purchased a Prequel test (the "California Subclass") (collectively with the Nationwide Class, "Class").
- 63. Specifically excluded from the Class are persons who made such purchase for the purpose of resale, Defendants, Defendants' officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals, servants, partners, joint ventures, or entities controlled by Defendants, and their heirs, successors, assigns, or other persons or entities related to or affiliated with Defendant and/or Defendant's officers and/or directors, the judge assigned to this action, and any member of the judge's immediate family.
- 64. Subject to additional information obtained through further investigation and discovery, the foregoing definition of the Class may be expanded or narrowed by amendment or amended complaint.

65. Numerosity. The members of the Class are geographically dispersed throughou					
the United States and are so numerous that individual joinder is impracticable. Upon					
information and belief, Plaintiff reasonably estimates that there are hundreds of thousands of					
members in the Class. Although the precise number of Class members is unknown to Plaintiff,					
the true number of Class members is known by Defendant and may be determined through					
discovery. Class members may be notified of the pendency of this action by mail and/or					
publication through the distribution records of Defendant and third-party retailers and vendors.					

- 66. Existence and predominance of common questions of law and fact. Common questions of law and fact exist as to all members of the Class and predominate over any questions affecting only individual Class members. These common legal and factual questions include, but are not limited to, the following:
 - (a) whether the Prequel manufactured, distributed, and sold by Defendant was unfit for use as screening test, thereby breaching express and implied warranties made by Defendant and making the Prequel Test unfit for its intended purpose;
 - (b) whether Defendant knew or should have known that Prequel was unreliable prior to selling the Tests, thereby constituting fraud and/or fraudulent omission;
 - (c) whether Defendant is liable to Plaintiff and the Class for unjust enrichment;
 - (d) whether Plaintiff and the Class have sustained monetary loss and the proper measure of that loss;
 - (e) whether Plaintiff and the Class are entitled to restitution and disgorgement from Defendants; and
 - (f) whether the marketing, advertising, packaging, labeling, and other promotional materials for Prequel are deceptive.
- 67. **Typicality.** Plaintiff's claims are typical of the claims of the other members of the Class in that Defendant mass marketed and sold unreliable Prequel tests to consumers throughout the United States. This unreliability was present in all of the Prequel tests manufactured, distributed, and sold by Defendants. Therefore, Defendant breached its express and implied warranties to Plaintiff and Class members by manufacturing, distributing, and

selling the unreliable Prequel tests. Plaintiff's claims are typical in that she was uniformly harmed in purchasing and using Prequel to test for Trisomy 13, for which Prequel was unreliable to test for. Plaintiff's claims are further typical in that Defendant deceived Plaintiff in the very same manner as they deceived each member of the Class. Further, there are no defenses available to Defendant that are unique to Plaintiff.

- 68. Adequacy of Representation. Plaintiff will fairly and adequately protect the interests of the Class. Plaintiff has retained counsel that is highly experienced in complex consumer class action litigation, and Plaintiff intends to vigorously prosecute this action on behalf of the Class. Furthermore, Plaintiff has no interests that are antagonistic to those of the Class.
- 69. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class members are relatively small compared to the burden and expense of individual litigation of their claims against Defendants. It would, thus, be virtually impossible for the Class, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if Class members could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances.
 - 70. In the alternative, the Class may also be certified because:
 - (a) the prosecution of separate actions by individual Class members would create a risk of inconsistent or varying adjudications with respect to individual members that would establish incompatible standards of conduct for the Defendant;
 - (b) the prosecution of separate actions by individual Class members

- would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other Class members not parties to the adjudications, or substantially impair or impede their ability to protect their interests; and/or
- (c) Defendant has acted or refused to act on grounds generally applicable to the Class as a whole, thereby making appropriate final declaratory relief with respect to the members of the Class as a whole.

CAUSES OF ACTION

COUNT I Breach Of Express Warranty

- 71. Plaintiff incorporates by reference the allegations contained in all preceding paragraphs of this complaint.
- 72. Plaintiff brings this claim individually and on behalf of the Class against Defendant.
 - This count is brought under the laws of the State of California. 73.
- 74. In connection with the sale of the Tests, Defendant, as the designer, manufacturer, marketers, distributor, and/or seller issued written warranties by representing that the Tests "ha[ve] the lowest test failure rate in the industry, which translates to a lower chance of needing a repeat test or an unnecessary invasive diagnostic procedure." Defendant further represents that its Tests are "more accurate than maternal serum screening," tells women that the Tests will "reduc[e] the chances you'll need an unnecessary invasive follow-up test," and assures women that they should have "total confidence" in every result.
- In fact, the Tests do not conform to the above-referenced representations because 75. the tests are unreliable, returning a large number of false positives for conditions like Trisomy 13, microdeletions, DiGeorge syndrome, and monosomy X.
- 76. Plaintiff and Class Members were injured as a direct and proximate result of Defendant's breaches because they would not have purchased the Tests if they had known that the Tests did not work as warranted.

SECOND AMENDED CLASS ACTION COMPLAINT CASE No. 4:22-cv-00739-YGR

77. On January 20, 2022, prior to the filing of this action, Defendant was served with a notice letter on behalf of Plaintiff and the Class that complied in all respects with U.C.C. §§ 2-313 and 2-607. Plaintiff's counsel sent Defendant a letter advising Defendant that it breached an express warranty and demanded that Defendant cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copy of this letter is attached hereto as **Exhibit 1**.

<u>COUNT II</u> Breach Of Implied Warranty

- 78. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.
- 79. Plaintiff brings this claim individually and on behalf of the members of the proposed Class against Defendant.
 - 80. This count is brought under the laws of the State of California.
- 81. Defendant, as the designer, manufacturer, marketer, distributor, and/or seller, impliedly warranted that the Tests were suited for use to detect chromosomal abnormalities with a high degree of accuracy. Defendant breached the warranty implied in the contract for the sale of the Tests because the Tests could not "pass without objection in the trade under the contract description," the Tests were not "of fair average quality within the description," the Tests were not "adequately contained, packaged, and labeled as the agreement may require," and the Tests did not "conform to the promise or affirmations of fact made on the container or label." *See* U.C.C. § 2-314(2) (listing requirements for merchantability). As a result, Plaintiff and Class Members did not receive the goods as impliedly warranted by Defendant to be merchantable.
- 82. Plaintiff and the Class Members purchased the Tests in reliance upon Defendant's skill and judgment in properly packaging and labeling the Tests.
 - 83. The Tests were not altered by Plaintiff and Class Members.
- 84. The Tests were not fit for their intended purpose when they left the exclusive control of Defendant.

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testing by Plaintiff and Class Members.

86. The Tests were defectively designed and unfit for their intended purpose, and

Defendant knew that the Tests would be purchased and used without additional

Plaintiff and Class Members did not receive the Tests as warranted.

87. Plaintiff and Class Members and Subclass Members were injured as a direct and proximate result of Defendant's breach because (i) they would not have purchased the Tests if they had known that the Tests were unreliable, highly inaccurate, not dependable, and therefore unsuitable for their stated and advertised purpose of detecting chromosomal abnormalities with a high degree of accuracy, and (ii) they overpaid for the Tests on account of its misrepresentations that it was capable of detecting chromosomal abnormalities with a high degree of reliability.

88. On January 20, 2022, prior to the filing of this action, Defendant was served with a notice letter on behalf of Plaintiff and the Class that complied in all respects with U.C.C. §§ 2-313 and 2-607. Plaintiff's counsel sent Defendant a letter advising Defendant that it breached an implied warranty and demanded that Defendant cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copy of this letter is attached hereto as **Exhibit 1**.

<u>COUNT III</u> Unjust Enrichment

- 89. Plaintiff incorporates by reference the allegations contained in all preceding paragraphs of this complaint.
- 90. Plaintiff brings this claim individually and on behalf of the members of the proposed Class against Defendant.
 - 91. This count is brought under the laws of the State of California.
- 92. Plaintiff and the Class conferred a benefit on Defendant in the form of monies paid to purchase Defendant's defective Prequel tests.
 - 93. Defendant voluntarily accepted and retained this benefit.
 - 94. Because this benefit was obtained unlawfully, namely by selling and accepting

- 95. Plaintiff and Class Members have no adequate remedy at law for this claim. Plaintiff pleads her claim for equitable relief in the alternative, which inherently would necessitate a finding of no adequate remedy at law.
- 96. Alternatively, legal remedies available to Plaintiff are inadequate because they are not "equally prompt and certain and in other ways efficient" as equitable relief. *American Life Ins. Co. v. Stewart*, 300 U.S. 203, 214 (1937); *see also United States v. Bluitt*, 815 F. Supp. 1314, 1317 (N.D. Cal. Oct. 6, 1992) ("The mere existence" of a possible legal remedy is not sufficient to warrant denial of equitable relief."); *Quist v. Empire Water Co.*, 2014 Cal. 646, 643 (1928) ("The mere fact that there may be a remedy at law does not oust the jurisdiction of a court of equity. To have this effect, the remedy must also be speedy, adequate, and efficacious to the end in view ... It must reach the whole mischief and secure the whole right of the party in a perfect manner at the present time and not in the future.").

97. Furthermore:

- (a) To the extent damages are available here, damages are not equally certain as restitution because the standard that governs ordering restitution is different than the standard that governs damages. Hence, the Court may award restitution even if it determines that Plaintiff fails to sufficiently adduce evidence to support an award of damages.
- (b) Damages and restitution are not necessarily the same amount. Unlike damages, restitution is not limited to the amount of money defendant wrongfully acquired plus the legal rate of interest. Equitable relief, including restitution, entitles the plaintiff to recover all profits from the wrongdoing, even where the original funds taken have grown far greater than the legal rate of interest would recognize. Plaintiff seeks such relief here.
- (c) Legal claims for damages are not equally certain as restitution because claims for unjust enrichment entail few elements.
- (d) A claimant otherwise entitled to a remedy for unjust enrichment, including a remedy originating in equity, need not demonstrate the inadequacy of available remedies at law." RESTATEMENT (THIRD) OF RESTITUTION § 4(2).

COUNT IV

- 98. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.
- 99. Plaintiff brings this claim individually and on behalf of the members of the proposed Class against Defendant.
 - 100. This count is brought under the laws of the State of California.
- 101. As discussed above, Defendant provided Plaintiff and Class members with materially false or misleading information about the Prequel tests manufactured, distributed, and sold by Defendant. Specifically, Defendant had knowledge of the fact that Prequel tests were unreliable, often result in false positive. Defendant nevertheless actively represented to consumers that the Prequel tests were reliable, trustworthy, and that consumers should have "total confidence" in every result.
- 102. The misrepresentations and omissions of material fact made by Defendant, upon which Plaintiff and Class members reasonably and justifiably relied, were intended to induce, and actually induced Plaintiff and Class members to purchase the unreliable Prequel tests.
- 103. The fraudulent actions of Defendant caused damage to Plaintiff and Class members, who are entitled to damages and other legal and equitable relief as a result.
- 104. As a result of Defendant's willful and malicious conduct, punitive damages are warranted.

COUNT V Fraudulent Omission

- 105. Plaintiff incorporates by reference the allegations contained in all preceding paragraphs of this complaint.
- 106. Plaintiff brings this claim individually and on behalf of the members of the proposed Class against Defendant.
 - 107. This count is brought under the laws of the State of California.
 - 108. As discussed above, Defendant failed to disclose that the Tests were unreliable to

test for a number of conditions like Trisomy 13 and microdeletions because Prequel frequently provides false positive results for these conditions.

- 109. The false and misleading omissions were made with knowledge or their falsehood. Defendant is a national genetics laboratory that specializes in genetic testing and therefore knew the Tests were unreliable and would provide an unnecessarily high number of false positive results. Nonetheless, Defendant continued to sell its worthless Tests to unsuspecting consumers.
- 110. The false and misleading omissions were made by Defendant, upon which Plaintiff and members of the proposed Class reasonably and justifiably relied, were intended to induce, and actually induced Plaintiff and Class Members to purchase the tests.
- 111. The fraudulent actions of Defendant caused damage to Plaintiff and Class Members, who are entitled to damages and punitive damages.

Violation of California's Unfair Competition Law

California Business and Professions Code §§ 17200, et seq.

- 112. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.
- 113. Plaintiff brings this claim individually and on behalf of the members of the California Subclass against Defendant.
 - 114. This count is brought under the laws of the State of California.
- 115. By committing the acts and practices alleged herein, Defendant has violated California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200, et seq., as to the California Subclass, by engaging in unlawful, fraudulent, and unfair conduct.
- 116. Defendant has violated the UCL's proscription against engaging in unlawful conduct as a result of its violations of the CLRA, FAL, and by committing fraud, unjust enrichment, and breaching express and implied warranties, as alleged herein.

- Drug, and Cosmetic Law, Cal. Health & Safety Code §§ 109875, et seq. (the "Sherman Food, Drug, and Cosmetic Law, Cal. Health & Safety Code §§ 109875, et seq. (the "Sherman Act"). Specifically, the Sherman Act prohibits the sale of misbranded drugs and devices. "Any drug or device is misbranded if its labeling is false or misleading in any particular." Sherman Act, Health & Safety Code § 111330. "Device' means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is ... [i]ntended for use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment, or prevention of disease in humans or any other animal." Id. § 109920(b). Here, the Prequel test fits within the definition of a "device" and are "misbranded" because its labeling—specifically, its representations that it is a reliable test—is false and misleading. Therefore, the marketing of the Prequel tests is violative of the Sherman Act and the unlawful provision of the UCL by extension.
- 118. Defendant's acts and practices described above also violate the UCL's proscription against engaging in fraudulent conduct. As more fully described above, Defendant's misleading marketing, advertising, packaging, and labeling of the Tests is likely to deceive reasonable consumers.
- 119. Plaintiff and the other California Subclass members suffered a substantial injury by virtue of buying the Tests that they would not have purchased absent Defendant's unlawful, fraudulent, and unfair marketing, advertising, packaging, and omission about the reliability of the Tests, or by virtue of paying an excessive premium price for the unlawfully, fraudulently, and unfairly marketed, advertised, packaged, and labeled Tests.
- 120. There is no benefit to consumers or competition from deceptively marketing and omitting material facts about the unreliable nature of the Tests.
- 121. Plaintiff and the other California Subclass members had no way of reasonably knowing that the Tests they purchased were not as marketed, advertised, packaged, or labeled. Thus, they could not have reasonably avoided the injury each of them suffered.

- 122. The gravity of the consequences of Defendant's conduct as described above outweighs any justification, motive, or reason therefore, particularly considering the available legal alternatives which exist in the marketplace, and such conduct is immoral, unethical, unscrupulous, offends established public policy, or is substantially injurious to Plaintiff and the other members of the California Subclass.
- 123. Plaintiff and California Subclass Members have no adequate remedy at law for this claim. Plaintiff pleads her claim for equitable relief in the alternative, which inherently would necessitate a finding of no adequate remedy at law.
- 124. Alternatively, legal remedies available to Plaintiff are inadequate because they are not "equally prompt and certain and in other ways efficient" as equitable relief. *American Life Ins. Co. v. Stewart*, 300 U.S. 203, 214 (1937); *see also United States v. Bluitt*, 815 F. Supp. 1314, 1317 (N.D. Cal. Oct. 6, 1992) ("The mere existence" of a possible legal remedy is not sufficient to warrant denial of equitable relief."); *Quist v. Empire Water Co.*, 2014 Cal. 646, 643 (1928) ("The mere fact that there may be a remedy at law does not oust the jurisdiction of a court of equity. To have this effect, the remedy must also be speedy, adequate, and efficacious to the end in view ... It must reach the whole mischief and secure the whole right of the party in a perfect manner at the present time and not in the future.").

125. Furthermore:

- (a) To the extent damages are available here, damages are not equally certain as restitution because the standard that governs ordering restitution is different than the standard that governs damages. Hence, the Court may award restitution even if it determines that Plaintiff fails to sufficiently adduce evidence to support an award of damages.
- (b) Damages and restitution are not necessarily the same amount. Unlike damages, restitution is not limited to the amount of money defendant wrongfully acquired plus the legal rate of interest. Equitable relief, including restitution, entitles the plaintiff to recover all profits from the wrongdoing, even where the original funds taken have grown far greater than the legal rate of interest would recognize. Plaintiff seeks such relief here.

- (c) Legal claims for damages are not equally certain as restitution because claims under the UCL entail few elements. Further, the "unlawful" prong of the UCL is the only way for Plaintiff to vindicate violations of the Sherman Act because the Sherman Act contains no private right of action.
- (d) A claimant otherwise entitled to a remedy for unjust enrichment, including a remedy originating in equity, need not demonstrate the inadequacy of available remedies at law." RESTATEMENT (THIRD) OF RESTITUTION § 4(2).

COUNT VII

Violation of California's False Advertising Law California Business and Professions Code §§ 17500, et seq.

- 126. Plaintiff incorporates by reference the allegations contained in all preceding paragraphs of this complaint.
- 127. Plaintiff brings this claim individually and on behalf of the members of the California Subclass against Defendant.
 - 128. This count is brought under the laws of the State of California.
- 129. Defendant has engaged in false or misleading advertising in violation of California's statutory False Advertising Law ("FAL").
- 130. Defendant's conduct as described herein is misleading, and/or has a capacity, likelihood or tendency to deceive reasonable consumers.
- 131. Defendant, with intent directly or indirectly to dispose of personal property or to perform services, or to induce the public to enter into any obligation relating thereto, makes, disseminates, has made or disseminated, causes to be made or disseminated, and/or has caused to be made or disseminated, before the public in California, in newspaper or other publication, or other advertising device, or by public outcry or by proclamation, or in any other manner or means, including over the internet, statements concerning that personal property or those services, and/or concerning any circumstance or matter of fact connected with the proposed performance or disposition thereof, which are untrue or misleading and which are known (or which by the exercise of reasonable care should be known) to be untrue or misleading.
 - 132. Defendant made, disseminated, makes, disseminates, caused to be made or

disseminated and/or causes to be made or disseminated any statements concerning the disposition of personal property or the performance of services, and/or concerning any circumstance or matter of fact connected with such statement as part of a plan or scheme with the intent not to sell that personal property or those services, professional or otherwise, as advertised.

- 133. With respect to omissions, Defendant at all relevant times had a duty to disclose the information in question because, *inter alia*: (a) Defendant had exclusive knowledge of material information that was not known to Plaintiff and the California Subclass; (b) Defendant concealed material information from Plaintiff and the California Subclass; and/or (c) Defendant made partial representations which were false and misleading absent the omitted information.
- 134. Defendant committed such violations of the FAL with actual knowledge that its advertising was misleading, or Defendant, in the exercise of reasonable care, should have known that its advertising was misleading.
- 135. Plaintiff and the California Subclass reasonably relied on Defendant's representations and/or omissions made in violation of the FAL.
- 136. As a direct and proximate result of Defendant's unfair, unlawful, and fraudulent conduct, Plaintiff and each member of the California Subclass suffered injury-in-fact and lost money.
- 137. But for Defendant's deceptive conduct and omissions of material facts, Plaintiff and the California Subclass would not have purchased the subject NIPT tests and/or would have purchased an appropriate NIPT test from one of Defendant's competitors instead.
- 138. Defendant should be ordered to disgorge or make restitution of all monies improperly accepted, received, or retained.
- 139. Plaintiff and California Subclass Members have no adequate remedy at law for this claim. Plaintiff pleads her claim for equitable relief in the alternative, which inherently would necessitate a finding of no adequate remedy at law.

140. Alternatively, legal remedies available to Plaintiff are inadequate because they are not "equally prompt and certain and in other ways efficient" as equitable relief. *American Life Ins. Co. v. Stewart*, 300 U.S. 203, 214 (1937); *see also United States v. Bluitt*, 815 F. Supp. 1314, 1317 (N.D. Cal. Oct. 6, 1992) ("The mere existence" of a possible legal remedy is not sufficient to warrant denial of equitable relief."); *Quist v. Empire Water Co.*, 2014 Cal. 646, 643 (1928) ("The mere fact that there may be a remedy at law does not oust the jurisdiction of a court of equity. To have this effect, the remedy must also be speedy, adequate, and efficacious to the end in view ... It must reach the whole mischief and secure the whole right of the party in a perfect manner at the present time and not in the future.").

141. Furthermore:

- (a) To the extent damages are available here, damages are not equally certain as restitution because the standard that governs ordering restitution is different than the standard that governs damages. Hence, the Court may award restitution even if it determines that Plaintiff fails to sufficiently adduce evidence to support an award of damages.
- (b) Damages and restitution are not necessarily the same amount. Unlike damages, restitution is not limited to the amount of money defendant wrongfully acquired plus the legal rate of interest. Equitable relief, including restitution, entitles the plaintiff to recover all profits from the wrongdoing, even where the original funds taken have grown far greater than the legal rate of interest would recognize. Plaintiff seeks such relief here.
- (c) Legal claims for damages are not equally certain as restitution because claims under the FAL entail few elements.
- (d) A claimant otherwise entitled to a remedy for unjust enrichment, including a remedy originating in equity, need not demonstrate the inadequacy of available remedies at law." RESTATEMENT (THIRD) OF RESTITUTION § 4(2).

COUNT VIII

Violation of California's Consumers Legal Remedies Act California Civil Code §§ 1750, et seq.

- 142. Plaintiff incorporates by reference the allegations contained in all preceding paragraphs of this complaint.
 - 143. Plaintiff brings this claim individually and on behalf of the members of the

California Subclass against Defendant.

- 144. This count is brought under the laws of the State of California.
- 145. Defendant is a "person," as defined by California Civil Code § 1761(c).
- 146. Plaintiff and members of the California Subclass are "consumers," as defined by California Civil Code § 1761(d).
- 147. The NIPT tests purchased by the Plaintiff and the members of the California Subclass are "goods" as defined by California Civil Code § 1761(a).
- 148. The purchases by the Plaintiff and the members of the California Subclass constitute "transactions," as defined by California Civil Code § 1761(e).
- 149. The unlawful methods, acts or practices alleged herein to have been undertaken by Defendant were all committed intentionally and knowingly. The unlawful methods, acts or practices alleged herein to have been undertaken by Defendant did not result from a *bona fide* error notwithstanding the use of reasonable procedures adopted to avoid such error.
- 150. Defendant's methods, acts and/or practices, including Defendant's misrepresentations, omissions, active concealment, and/or failures to disclose, violated and continue to violate the CLRA in ways including, but not limited to, the following:
 - (a) Defendant misrepresented that its products had characteristics, benefits, or uses that they did not have (Cal. Civ. Code § 1770(a)(5));
 - (b) Defendant misrepresented that its products were of a particular standard, quality, grade, or of a particular style or model when the products were of another (Cal. Civ. Code § 1770(a)(7));
 - (c) Defendant advertised its products with an intent not to sell them as advertised (Cal. Civ. Code § 1770(a)(9)); and
 - (d) Defendant represented that its products were supplied in accordance with previous representations when they were not (Cal. Civ. Code § 1770(a)(16)).
- 151. Specifically, Defendant advertised and represented that the Tests were suitable for the particular purpose when in fact the Tests were not as reliable stated to test for conditions like Trisomy 13, microdeletions, DiGeorge syndrome, and monosomy X.

- 152. With respect to omissions, Defendant at all relevant times had a duty to disclose the information in question because, *inter alia*: (a) Defendant had exclusive knowledge of material information that was not known to Plaintiff and the California Subclass; (b) Defendant concealed material information from Plaintiff and the California Subclass; and/or (c) Defendant made partial representations which were false and misleading absent the omitted information.
- 153. Defendant's misrepresentations and nondisclosures deceive and have a tendency and ability to deceive the general public.
- 154. Defendant's misrepresentations and nondisclosures are material, in that a reasonable person would attach importance to the information and would be induced to act on the information in making purchase decisions. Indeed, the utility and value of Defendant's Tests are significantly reduced, to the point of worthlessness, because these tests should not and cannot be used for their intended and advertised purpose.
- 155. As a direct and proximate result of Defendant's unfair, unlawful, and fraudulent conduct, Plaintiff and the California Subclass suffered injury-in-fact and lost money.
- 156. Plaintiff and California Subclass Members have no adequate remedy at law for this claim. Plaintiff pleads her claim for equitable relief in the alternative, which inherently would necessitate a finding of no adequate remedy at law.
- 157. Alternatively, legal remedies available to Plaintiff are inadequate because they are not "equally prompt and certain and in other ways efficient" as equitable relief. *American Life Ins. Co. v. Stewart*, 300 U.S. 203, 214 (1937); *see also United States v. Bluitt*, 815 F. Supp. 1314, 1317 (N.D. Cal. Oct. 6, 1992) ("The mere existence" of a possible legal remedy is not sufficient to warrant denial of equitable relief."); *Quist v. Empire Water Co.*, 2014 Cal. 646, 643 (1928) ("The mere fact that there may be a remedy at law does not oust the jurisdiction of a court of equity. To have this effect, the remedy must also be speedy, adequate, and efficacious to the end in view ... It must reach the whole mischief and secure the whole right of the party in a perfect manner at the present time and not in the future.").

158. Furthermore:

- (a) To the extent damages are available here, damages are not equally certain as restitution because the standard that governs ordering restitution is different than the standard that governs damages. Hence, the Court may award restitution even if it determines that Plaintiff fails to sufficiently adduce evidence to support an award of damages.
- (b) Damages and restitution are not necessarily the same amount. Unlike damages, restitution is not limited to the amount of money defendant wrongfully acquired plus the legal rate of interest. Equitable relief, including restitution, entitles the plaintiff to recover all profits from the wrongdoing, even where the original funds taken have grown far greater than the legal rate of interest would recognize. Plaintiff seeks such relief here.
- (c) Legal claims for damages are not equally certain as restitution because claims under the FAL entail few elements.
- (d) A claimant otherwise entitled to a remedy for unjust enrichment, including a remedy originating in equity, need not demonstrate the inadequacy of available remedies at law." RESTATEMENT (THIRD) OF RESTITUTION § 4(2).
- Defendant a CLRA notice letter, which complies in all respects with California Civil Code § 1782(a). The letter also provided notice of breach of express and implied warranties. The letter was sent via certified mail, return receipt requested, advising Defendant that it was in violation of the CLRA and demanding that it cease and desist from such violations and make full restitution by refunding the monies received therefrom. The letter stated that it was sent on behalf of Plaintiff and all other similarly situated purchasers. Defendant failed to correct its business practices or provide the requested relief within 30 days. Accordingly, Plaintiff and the California Subclass now also seek monetary damages under the CLRA. A true and correct copy of the letter is attached hereto as **Exhibit 1**.
- 160. With regard to this count of the pleading which alleges one or more violations of the CLRA, venue is proper in the state or federal court having jurisdiction over Santa Clara County, California (the county in which this action has been commenced) pursuant to Section 1780(d) of the California Civil Code because, without limitation, Santa Clara County is a county in which

1	Defendant is doing business and is the county in which a substantial portion of the events that gave			
2	rise to this cause of action occurred. A declaration establishing that this Court has proper venue			
3	for this count is attached hereto as Exhibit 2 .			
4	PRAYER FOR RELIEF			
5	WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, seeks			
6	judgment against Defendants, as follows:			
7 8	(a)	(a) For an order certifying the nationwide Class under Rule 23 of the Federal Rules of Civil Procedure, naming Plaintiff as representative of the Class, and naming Plaintiff's attorneys as Class Counsel to represent the Class;		
9 10	(b)	(b) For an order declaring the Defendants' conduct violates the statutes referenced herein;		
11	(c)	For an order finding in favor herein;	of Plaintiff and the Class on all counts asserted	
12	(d)	For compensatory, statutory, by the Court and/or jury;	and punitive damages in amounts to be determined	
14	(e)	For prejudgment interest on a	all amounts awarded;	
15	(f)	For an order of restitution and all other forms of equitable monetary relief; and		
16	(g)	For an order awarding Plaintiff and the Class their reasonable attorneys' fees and expenses and costs of suit.		
17	DEMAND FOR TRIAL BY JURY			
18	Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of any		ocedure 38(b), Plaintiff demands a trial by jury of any	
19	and all issues in this action so triable of right.			
20	Dated: Augu	ust 16, 2022	Respectfully submitted,	
21			BURSOR & FISHER, P.A.	
22			By: <u>/s/ L. Timothy Fisher</u> L. Timothy Fisher	
23			L. Timothy Fisher (State Bar No. 191626)	
24			1990 North California Boulevard, Suite 940 Walnut Creek, CA 94596	
25			Telephone: (925) 300-4455 Facsimile: (925) 407-2700	
26			E-Mail: ltfisher@bursor.com	
27				
28				

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BURSOR FISHER

888 SEVENTH AVENUE NEW YORK, NY 10019 www.bursor.com JOSHUA ARISOHN Tel: 646.837.7103 Fax: 212.989.9163 jarisohn@bursor.com

January 20, 2022

Via Fed Ex and Certified Mail - Return Receipt Requested

Myriad Genetics, Inc. 320 Wakara Way Salt Lake City, UT 84108

CT Corporation System 1108 E South Union Ave Midvale, UT 84047

Re: Demand Letter Pursuant to California Civil Code § 1782; U.C.C. §§ 2-313, 2-314; and all other applicable laws

To Whom It May Concern:

This letter serves as a preliminary notice and demand for corrective action by Myriad Genetics, Inc. ("You" or "Defendant") pursuant to numerous provisions of California law, including but not limited to subsections (a)(5), (7), and (9) of the Consumers Legal Remedies Act, Civil Code § 1770 and U.C.C. § 2-607(3)(A) concerning the breaches of warranty described herein on behalf of our client, Ashley Carroll, and all other similarly situated purchasers.

You have participated in the marketing and sale of the Prequel Prenatal Screen (the "Product"). Defendant markets and sells the Tests as genetic, prenatal screening tests for pregnant women that screen for various chromosomal and genetic conditions affecting a baby's health. Defendant markets these tests as safe and accurate. However, these tests are incorrect about 85 percent of the time, subjecting expecting mothers to further diagnostic testing, genetic counseling, and the potential for erroneous termination of a viable pregnancy. Thus, the Product is unsuitable for its intended and advertised purpose, and Your representations are false and misleading.

Ms. Carroll purchased the Product based on the Product's representations.

Ms. Carroll is acting on behalf of a class defined as all persons in the United States who purchased the Product. Ms. Carroll is also acting on behalf of a subclass of persons who purchased the Product in the State of California.

To cure these defects, we demand that you make full restitution to all purchasers of the Product of all money obtained from sales thereof.

We further demand that you preserve all documents and other evidence which refer or relate to any of the above-described practices including, but not limited to, the following:

- 1. All documents concerning the design, development, and/or testing of the Product;
- 2. All documents concerning the advertisement, labeling, marketing, or sale of the Product;
- 3. All documents concerning communications with purchasers of the Product, including but not limited to customer complaints; and
- 4. All documents concerning your total revenue derived from sales of the Product in California and the United States.
- 5. All communications with the FDA and other regulatory agencies about the Product.

If you contend that any statement in this letter is inaccurate in any respect, please provide us with your contentions and supporting documents immediately upon receipt of this letter.

Please contact me right away if you wish to discuss an appropriate way to remedy this matter. If I do not hear from you promptly, I will take that as an indication that you are not interested in doing so.

Very truly yours,

Joshua D. Arisohn

CLRA Venue Declaration Pursuant to California Civil Code Section 1780(d)

I, L. Timothy Fisher, declare as follows:

- 1. I am counsel for Plaintiff, and I am a partner at Bursor & Fisher, P.A. I make this declaration to the best of my knowledge, information, and belief of the facts stated herein.
- 2. The complaint filed in this action is filed in the proper place for trial under California Civil Code Section 1780(d) because a substantial part of the events or omissions giving rise to these claims occurred in this District.
- 3. Plaintiff Ashley Carroll alleges that in or about June 2021, she purchased Defendant Myriad Genetics, Inc.'s ("Defendant") Prequel Test with AMPLIFY technology in California. *See* Compl. ¶ 9. Plaintiff further alleges that she purchased the Prequel Test because Defendant described the Prequel Test as reliable. Specifically, Defendant represented in its brochure that the Prequel Test is "more accurate than maternal serum screening" and will "reduc[e] the chances you'll need an unnecessary invasive follow-up test." Defendant's website also stated that Prequel "has the lowest test failure rate in the industry, which translates to a lower chance of needing a repeat test or an unnecessary invasive diagnostic procedure," and that Plaintiff should have "total confidence in every result." that the Prequel Test "has the lowest test failure rate in the industry, which translates to a lower chance of needing a repeat test or an unnecessary invasive diagnostic procedure."
- 4. Plaintiff reviewed Defendant's representations in California and relied on the same representations and warranties in deciding to purchase the Prequel Test. Accordingly, Defendant's representations and warranties were part of the basis of the bargain, in that she would not have purchased the Prequel Test on the same terms had she known the Test's representations about reliability and trustworthiness were not true, or at least would have paid significantly less for the Prequel Test.

I declare under the penalty of perjury under the laws of the United States and the State of California that the foregoing is true and correct. Executed on August 16, 2022 in Walnut Creek, California. /s/ L. Timothy Fisher L. Timothy Fisher